

We claim:

1. A crystalline imatinib mesylate form H1, characterized by an x-ray powder diffraction spectrum having peaks expressed as  $2\theta$  at about 9.9, 11.1, 16.3, 5 17.3, 18.1, 19.1, 19.6, 20.3, 21.1, 21.9, 23.2, 23.6, 24.2, 24.9, 25.6, 26.0, 27.3, 27.9, 28.9, 29.4, 30.4 and 30.5 degrees.
2. A crystalline imatinib mesylate form H1 as defined in claim 1, further characterized by a x-ray powder diffraction spectrum as in figure 1.
3. A process for preparation of imatinib mesylate form H1 as defined in claim 1, 10 which comprises the steps of:
  - a) dissolving imatinib free base in a chlorinated solvent;
  - b) adding methanesulfonic acid; and
  - c) isolating imatinib mesylate form H1 by filtration or centrifugation; wherein the chlorinated solvents is selected from chloroform, methylene dichloride, ethylene dichloride and a mixture thereof.
4. A process according to claim 3, wherein the chlorinated solvent is chloroform.
5. A process according to claim 3, wherein the chlorinated solvent is methylene dichloride.
- 20 6. A process for preparation of imatinib mesylate form H1 as defined in claim 1, which comprises the steps of:
  - a) mixing imatinib mesylate and a chlorinated solvent; and
  - b) isolating imatinib mesylate form H1 by filtration or centrifugation; wherein the chlorinated solvent is selected from chloroform, methylene dichloride, ethylene dichloride and a mixture thereof.
7. A process according to claim 6, wherein the chlorinated solvent is chloroform.
8. A process according to claim 6, wherein the chlorinated solvent is methylene dichloride.
- 30 9. Imatinib mesylate hydrate.
10. Imatinib mesylate hydrate of claim 9, wherein water content of the hydrate of imatinib mesylate is between 2.0 to 3.2% by weight of hydrate of imatinib mesylate.

11. Imatinib mesylate hydrate of claim 10, wherein water content of the hydrate of imatinib mesylate is between 2.2 to 2.9% by weight of hydrate of imatinib mesylate.
12. Imatinib mesylate hydrate of claim 11, wherein water content of the hydrate of imatinib mesylate is about 2.5% by weight of hydrate of imatinib mesylate.
- 5 13. A process for preparation of imatinib mesylate hydrate of claim 9, which comprises the steps of:
  - a) dissolving imatinib mesylate in a mixture of a suitable solvent and water;
  - b) removing the solvents from the solution formed in (a) either by vacuum
- 10 14. A process according to claim 13, wherein the solvent is removed by vacuum drying.
- 15 15. A process according to claim 13, wherein the solvent is removed by spray drying.
16. A process according to claim 13, wherein the alcohol is selected from methanol, ethanol and isopropyl alcohol; and the ketone is acetone.
17. A process according to claim 13, wherein the suitable solvent is methanol.
- 20 18. A process according to claim 13, wherein the suitable solvent is ethanol.
19. Amorphous imatinib mesylate hydrate.
20. Amorphous imatinib mesylate hydrate of claim 19 characterized by a x-ray powder diffraction spectrum as in figure 2.
21. Amorphous imatinib mesylate hydrate of claim 19, produced according to the
- 25 22. A pharmaceutical composition comprising imatinib mesylate form H1 of claim 1 and a pharmaceutically acceptable carrier or diluent.
23. A pharmaceutical composition comprising imatinib mesylate hydrate of claim 9 and a pharmaceutically acceptable carrier or diluent.
- 30 24. A pharmaceutical composition comprising amorphous imatinib mesylate hydrate of claim 19 and a pharmaceutically acceptable carrier or diluent.